

REMARKS

Claims 20-22 have been canceled without prejudice or disclaimer as being drawn to a non-elected invention. The applicant reserves the right to pursue these claims or other claims supported by the patent specification and drawings in one or more continuing or divisional applications. Claims 1, 6, 10, 23, and 28 have been amended. Claims 1-19 and 23-29 remain in the application.

The amendment to claim 23 addresses the rejection under 35 U.S.C. 112, second paragraph. Specifically, the word "can" has been replaced with "is". Claims 23-29 should now satisfy the requirements of 35 U.S.C. 112, second paragraph.

The amendments to claims 6 and 28 provide for proper antecedent basis.

One of the issues which appears to have been overlooked is that the invention requires pressurization of the collection vessel (see, e.g., "35" in Figure 1). To highlight this, independent claims 1, 10 and 23 specify that the collection vessel is pressurized to at least twice atmospheric pressure. Support for this can be found in the application on page 8, lines 4 and 5. As explained on page 8, the collection vessel would likely be pressurized far more than 2X atmospheric (e.g., 20X to 300X or more may be used as is explained on page 8 of the application). With reference to Figures 3-7 of the application and the paragraph on page 7, lines 10-21, it can be seen that when fibers are spun under ambient conditions (Figures 3 and 4) they have quite different characteristics than those made when electrospun under pressure (Figures 5-7). Table 2 on pages 12 and 13 of the application demonstrate that without pressure provided by CO₂ in the collection vessel, polyvinylpyrrolidone does not spin into fibers, i.e., the first entry shows that only droplets are sprayed from the needle whether there is zero CO₂ pressure in the spinning vessel, but that when there is CO₂ pressure in the vessel fibers are formed. Results are particularly good when both the mixing vessel and the spinning vessel are pressurized, and most preferably when the mixing vessel has more pressure than the collection vessel.

The invention provides a distinct advantage that the fibers produced by the inventive technique are essentially free of organic solvents (see page 14, lines 13-18)

that might otherwise adversely impact the fibers, and electrospinning may be achieved without a solvent (see page 5, lines 11 and 31, and page 6, line 27). Further, non-volatile solvents could be used in electrospinning (see page 6, line 28). Another advantage is that refractory polymers (i.e., those which are difficult to dissolve) may be electrospun with the present invention (see page 4, line 22).

Claims 23-28 were rejected as being anticipated by U.S. Patent Publication 2003/0168756 to Balkus. Claims 1-19 were rejected as being obvious over Balkus. Claim 29 was rejected as being obvious over Balkus in view of U.S. Patent Publication 2004/0094. These rejections are traversed.

Balkus does not show or suggest the essential features of the invention. Balkus does not pressurize the collection vessel in an electrospinning operation as is required in each of the independent claims. Moreover, Balkus does not pressurize the polymeric formulation.

Balkus uses pressure to push a polymer solution through a needle to perform electrospinning. Paragraphs 0006 and 0007, cited in the office action, are in the Background section of Balkus and basically describe electrospinning at a high level as it is understood in the trade. Notably, paragraph 0006 discuss using an solvent which evaporates. Balkus does not show or suggest using a non-volatile solvent, or not using a solvent at all, or using a supercritical fluid in combination with a solvent, all of which are set forth in the dependent claims of the present application.

Paragraph 0019 in Balkus offers that "The rate can be controlled by maintaining the conducting fluid at a constant pressure or flow rate...In other embodiments of the invention, the conducting solution introduction device comprises a glass pipette..." The crux of Balkus's invention is to use pressurized fluid or gas to push a polymer through a needle. Moreover, the pressure needed for this process is so low that a glass pipette can be used. More importantly, Balkus makes no statements that the pressurizing fluid has any "physical" effect on the polymer solution. Rather, in sharp contrast to the present invention, in Balkus, the pressurizing fluid just pushes the solution. Balkus does not invoke the unique action of a pressurized fluid when present in the collection vessel. Again, his use of pressure is just mechanical and is

primarily used to control flow rates as stated in paragraph 0056, "... at a constant pressure or constant flow rate. ... glass pipette ..."

In contrast to Balkus, as explained on page 6, lines 9-17, the invention uses the unique properties of a compressed gas at high pressures to "treat" the fiber. In the paragraph on page 3, lines 13-24 it is stated "In one embodiment, a pressurized polymer formulation optionally containing an organic solvent and/or a pressurized or supercritical fluid is electrospun into a pressurized collection vessel such that **polymer fibers are formed essentially free of said organic solvent.** In another embodiment, a liquid polymeric formulation containing at least one fiber-forming polymer dissolved or dispersed in at least one organic solvent is electrospun into a collection vessel such that polymer fibers are formed on a target in the collection vessel, **the interior of the collection vessel containing a pressurized or supercritical fluid and the collected fibers being essentially free of the organic solvent which has been extracted by the pressurized or supercritical fluid.** In another embodiment, a pressurized pure polymer melt optionally containing a pressurized or supercritical fluid is electrospun into the pressurized collection vessel." (Emphasis added)

On page 4, lines 16-23 of the patent application, the unique role of the pressurizing fluid is discussed "**By use of a pressurized formulation and pressurized collection vessel, polymeric formulations can be electrospun despite viscosities which are too high for successful electrospinning under ambient conditions. Moreover, nonvolatile organic solvents can be used.** In conventional electrospinning techniques, the solvent for the polymer must be sufficiently volatile to be vaporized during electrospinning at atmospheric pressure. **A pressurized environment and the use of pressurized fluids enables one to electrospin refractory polymers, i.e. polymers that are difficult to dissolve in solution or that do not melt even at high temperatures.**" (Emphasis added) page 6, line 19 et seq., and page 7, line 22 et seq. also discuss viscosity reduction, an issue never mentioned by Balkus.

In the application, in the paragraph bridging pages 6 and 7, it is described how

the fiber morphology can be changed due to the high-pressure operating conditions, "It has also been observed that the **pressurized or supercritical conditions maintained in the electrospinning apparatus have an effect on the morphology of the fibers.** Thus, by varying temperatures and/or pressures, fibers can be obtained which are discontinuous and flat or are open-cell with a surrounding ruptured or non-ruptured skin or have an open-cell internal structure with no surrounding skin. By controlling process parameters it is possible to produce a desired pore size in the electrospun fibers." (Emphasis added) The pressurized fluid extracts the solvent from the polymer solution jet. When this happens the polymer hardens or vitrifies, which sets in a unique open morphology. Balkus makes no such disclosure. This lack of disclosure is not surprising since those skilled in the art would know that a pressurizing fluid at low pressures will not behave as a good solvent and, therefore, will have no effect on the polymer fiber.

Furthermore, the Examiner's conclusions on page 5 of the office action are simply incorrect. Using a gas to move a polymer through a needle does NOT pressurize the collection vessel (the Examiner has recognized that Balkus does not explicitly recite the collection vessel is pressurized but then erroneously suggests doing so would be obvious—How so? In Balkus, the collection vessel is not pressurized at all—Balkus merely is using pressure to move the polymer through a needle and is not pressurizing the collection vessel at all).

As the claims better highlight that the collection vessel is pressurized (to at least twice atmospheric pressure) and that the polymer is pressurized, and none of these requirements are shown or alluded to in either Balkus or Dubson, none of the claims are anticipated or would be obvious to one of ordinary skill in the art.

In view of the foregoing, it respectfully requested that the application be reconsidered, that claims 1-19 and 23-29 be allowed, and the application be passed to issue.

Should the Examiner find the application to be other than in condition for allowance, the Examiner is requested to contact the undersigned at the local telephone number listed below to discuss any other changes deemed necessary in a telephonic or

personal interview.

A provisional petition is hereby made for any extension of time necessary for the continued pendency during the life of this application. Please charge any fees for such provisional petition and any deficiencies in fees and credit any overpayment of fees to Attorney's Deposit Account No. 50-2041.

Respectfully submitted,



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